



DECLARATION OF CONFORMITY

Manufacturer:

Luropas del dottor Molinari & C. Srl
Via Vivaldi 4
24040 Calvenzano (BG) – Italy

We, the manufacturer, herewith declare that the following products:

ITEM CODE	PRODUCT NAME	INDED USE	DEVICE CLASS	CND CODES	BASIC UDI-DI
430BEI	GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 1 GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 2 GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 3 GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 4 GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 5 GAMBALETTO MICROFIBRE K1 APERTO BEIGE – SIZE 6	K1 – K2 therapeutic hosiery, open toe. Recommended for the treatment of the venous insufficiency, also chronic, with development of varicose veins, formation of phlebitis, oedema, and varicose ulcers. Efficient in case of thrombophlebitis, postoperative prophylaxis, surgical operations on varicose veins, sclerotherapy and trauma and fractures of the lower limbs.	I, Rule 1 (Annex VIII of MDR2017/745)	M030405	803261520SLUROPAS6H
431BEI	AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 1 AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 2 AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 3 AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 4 AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 5 AUTOREGGENTE MICROFIBRE K1 APERTO BEIGE – SIZE 6			M030405	
432BEI	COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 1 COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 2 COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 3 COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 4 COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 5 COLLANT MICROFIBRE K1 APERTO BEIGE – SIZE 6			M030405	
434BEI	GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 1 GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 2 GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 3 GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 4 GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 5 GAMBALETTO MICROFIBRE K1 CHIUSO BEIGE – SIZE 6			M030405	
435BEI	AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 1 AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 2 AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 3 AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 4 AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 5 AUTOREGGENTE MICROFIBRE K1 CHIUSO BEIGE – SIZE 6			M030405	
436BEI	COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 1 COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 2 COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 3 COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 4 COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 5 COLLANT MICROFIBRE K1 CHIUSO BEIGE – SIZE 6			M030405	
440BEI	GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 1 GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 2 GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 3 GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 4 GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 5 GAMBALETTO MICROFIBRA K2 APERTO BEIGE – SIZE 6			M030405	
440NER	GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 1 GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 2 GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 3 GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 4 GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 5 GAMBALETTO MICROFIBRA K2 APERTO NERO – SIZE 6			M030405	
441BEI	AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 1 AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 2 AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 3 AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 4 AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 5 AUTOREGGENTE MICROFIBRA K2 APERTO BEIGE – SIZE 6			M030405	
441NER	AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 1			M030405	

	AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 2 AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 3 AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 4 AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 5 AUTOREGGENTE MICROFIBRA K2 APERTO NERO – SIZE 6				
442BEI	COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 1 COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 2 COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 3 COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 4 COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 5 COLLANT MICROFIBRA K2 APERTO BEIGE – SIZE 6			M030405	
442NER	COLLANT MICROFIBRA K2 APERTO NERO – SIZE 1 COLLANT MICROFIBRA K2 APERTO NERO – SIZE 2 COLLANT MICROFIBRA K2 APERTO NERO – SIZE 3 COLLANT MICROFIBRA K2 APERTO NERO – SIZE 4 COLLANT MICROFIBRA K2 APERTO NERO – SIZE 5 COLLANT MICROFIBRA K2 APERTO NERO – SIZE 6			M030405	
443BEI	GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 1 GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 2 GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 3 GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 4 GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 5 GAMBALETTO MICROFIBRA K2 CHIUSO BEIGE – SIZE 6			M030405	
443NER	GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 1 GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 2 GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 3 GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 4 GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 5 GAMBALETTO MICROFIBRA K2 CHIUSO NERO – SIZE 6			M030405	
444BEI	AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 1 AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 2 AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 3 AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 4 AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 5 AUTOREGGENTE MICROFIBRA K2 CHIUSO BEIGE – SIZE 6			M030405	
444NER	AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 1 AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 2 AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 3 AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 4 AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 5 AUTOREGGENTE MICROFIBRA K2 CHIUSO NERO – SIZE 6			M030405	
445BEI	COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 1 COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 2 COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 3 COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 4 COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 5 COLLANT MICROFIBRA K2 CHIUSO BEIGE – SIZE 6			M030405	
445NER	COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 1 COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 2 COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 3 COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 4 COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 5 COLLANT MICROFIBRA K2 CHIUSO NERO – SIZE 6			M030405	

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable standards:

UNI EN ISO 13485:2016
UNI CEI EN 15223-1:2017
ISO 14971:2019
ISO 10993-1: 2018
ISO 10993-5: 2018

We, the manufacturer, herewith declare under our own responsibility, that our above-mentioned products meet the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Natale Molinari

Stamp and signature

Date: 27/5/2021

Place: Calvenzano (BG), Italy


LUROPAS
del dott. Molinari & C. s.r.l.
Cap. Soc. € 45.000,00 i.v.
Via Viviani, 4 - 24040 CALVENZANO (BG)
Tel. 0363 86666 - Fax 0363 85281
Cod. Fisc. e Partita IVA 00683840169